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EXHIBIT #4 APR 23 1997

510(k) Summary

Kendall Hydrophilic Powder Wound Dressing

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall Healthcare Products Company
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Date Prepared: April 21, 1997

1 Contact Person

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2 Name of Medical Device

Classification Name: Unclassified
Common or Usual Name: Hydrophilic Powder Wound Dressing

3 Identification of Legally Marketed Device

The proposed Kendall Hydrophilic Powder Wound Dressing is substantially equivalent in intended use and composition to the commercially available DeRoyal Multidex® Hydrophilic Powder Wound Dressing, 510(k) No. K945000.

4 Device Description

The proposed Kendall Hydrophilic Powder Wound Dressing is a sterile composition of maltodextrin, sodium alginate and chitosan chloride. As the powder absorbs wound exudate it converts to a gel. This gel forms a moist environment at the wound interface conducive to healing. The product is available in 6 gram, 12 gram and 25 gram packets.

5 Device Intended Use

Like the predicate device, the Kendall Hydrophilic Powder Wound Dressing is indicated for the management of exudating wounds such as dermal ulcers (e.g., venous stasis, pressure, arterial, diabetic), surgical incisions, traumatic wounds (e.g., lacerations, abrasions).

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6 Product Comparison

The Kendall Hydrophilic Powder Wound Dressing is equivalent to the referenced predicate device in that they are fabricated from similar materials, have a similar function and equivalent indications for use.

7 Nonclinical Testing

Biocompatibility testing of the Kendall Hydrophilic Powder Wound Dressing has demonstrated that it contains no bioactive components. Testing performed on the product was based upon guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.